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5 **UNITED STATES DISTRICT COURT**
6 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
7 **SAN FRANCISCO DIVISION**

8 IN RE: BABY FOOD PRODUCTS
9 LIABILITY LITIGATION

Case No. 24-MD-3101-JSC

MDL 3101

10 J.M., a minor child by and through her
11 Proposed Guardian Ad Litem, Andrea
12 Sherwood,

Hon. Jacqueline Scott Corley

13 *Plaintiff,*

COMPLAINT AND JURY DEMAND

Case No.

14 vs.

15 BEECH-NUT NUTRITION COMPANY,
16 INC.; HERO A.G.; GERBER PRODUCTS
17 COMPANY; NESTLÉ HOLDINGS, INC.;
18 NESTLÉ S.A.; and WALMART, INC.

19 *Defendants.*

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21 Plaintiff by and through their counsel of record, and for their Complaint against
22 Defendants, hereby alleges as follows:
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INTRODUCTION

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2 1. Defendants *knowingly* sold baby food products contaminated with lead, arsenic,
3 mercury, and cadmium (collectively “Toxic Heavy Metals”). They did this knowing that Toxic
4 Heavy Metals, when consumed by babies, are known to cause brain damage and
5 neurodevelopmental harm. Thus, to the extent Defendants sold baby food that contained detectable
6 amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those products were
7 defective in their manufacture, design, and labeling. Babies are the most vulnerable segment of the
8 population, and they rely on that food for healthy neurodevelopment. Defendants justify this callous
9 disregard for the welfare of babies because, until recently, there were no regulations governing the
10 presence of Toxic Heavy Metals in baby foods – and, because there were no regulations, they were
11 free to do as they pleased.

14 2. This lawsuit aims to stop Defendants from poisoning infants with Contaminated
15 Baby Food. Baby Food *should* be safe. It should *not* be contaminated with Toxic Heavy Metals.
16 Period. By sourcing ingredients from farms that have non-detectable level of heavy metal (using
17 sufficiently sensitive testing), avoiding certain ingredients all together, and systematically testing
18 and screening finished products for Toxic Heavy Metals *before* the foods are released for
19 consumption, these Defendants would be able to provide baby food products of detectable levels of
20 Toxic Heavy Metals. And, if some levels are truly unavoidable, or if Defendants believe the
21 identified levels are safe, then, at the very least, Defendants must warn parents/guardians/caregivers
22 about the presence of these Toxic Heavy Metals so they can make informed decisions about what
23 they are feeding their baby. Anything short of proper design, manufacture, and warning, is
24 unacceptable – especially for an industry that touts itself as providing the most important sources of
25 neurodevelopment for the most vulnerable population of society.
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3. Plaintiff, here is a child that lives with brain injuries and neurodevelopmental harm caused by exposure to the Defendants' Contaminated Baby Food, which has manifested in a diagnosis of ASD and ADHD. Her parents were never warned that the Defendants' food contained Toxic Heavy Metals and, thus, were never able to make an informed decision about whether to feed their child Defendants' Contaminated Baby Foods. The consequences are stark- there is an unprecedented epidemic of ASD and ADHD spreading throughout the American population, driven, in part, by the systematic neurodevelopmental poisoning of infants from these Defendants' Contaminated Baby Foods.

PLAINTIFF'S EXPERIENCES AND INJURIES

4. On or about January 2013, Plaintiff J.M. was first exposed to the Contaminated Baby Food.

5. Plaintiff J.M. consumed Contaminated Baby Food Products from approximately January 2013 to September 2014.

6. Plaintiff J.M. consumed the Contaminated Baby Food Products while residing in Nassau County New York.

7. The Contaminated Baby Food was purchased and consumed at least three times per day by Plaintiff J.M., a minor child, with the purpose of nutrition, the use for which Defendants marketed and sold the products.

8. At all times, the Contaminated Baby Food was consumed by Plaintiff J.M. for the purposes that Defendants market the Baby Food Products.

9. After, and as a result of the consumption of Contaminated Baby Foods, Plaintiff J.M. was diagnosed with ASD and ADHD on or about November 2020.

10. As a result of consuming Contaminated Baby Food, the diagnosis of ASD and

1 ADHD has required various therapies including Speech Therapy, Occupational Therapy, Physical
2 Therapy,
3 and Applied Behavior Analysis Therapy.
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5 11. As a result of the aforesaid conduct and the Contaminated Baby Food products
6 manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiff J.M., a minor
7 child, has sustained injury to her person. Plaintiff is informed and believes, and allege thereon, that
8 such injuries will result in permanent disability to Plaintiff J.M., a minor child. As a result of such
9 injury, Plaintiff has suffered general damages in an amount within the jurisdiction of this Court.
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11 12. As a further result of the aforesaid conduct and defective product manufactured, sold,
12 distributed, advertised, and promoted by Defendants, Plaintiff J.M., a minor child was required to
13 and did incur additional medical costs by the necessity for multiple types of therapy. Further,
14 Plaintiff is informed and believes, and alleges thereon, that Plaintiff will be required to incur
15 additional medical expenses thereto, all according to proof.
16

17 **PARTIES**

18 13. Plaintiff J.M. (“JM”) is a minor child residing in Marion County, Florida who
19 consumed Defendants’ Baby Food products that contained unsafe levels of Toxic Heavy Metals.
20 ANDREA SHERWOOD is the legal guardian of JM and brings this action on her behalf. She is a
21 resident of Marion County, Florida and purchased toxic baby food from the Defendants for JM.
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23 14. Defendant BEECH-NUT NUTRITION COMPANY INC. (“Beech-Nut”) is a citizen of
24 Delaware and New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, NY
25 12010. Beech-Nut is wholly owned, controlled, and operated by the Hero Group, which considers
26 Beech-Nut to be one of its brands. In the Hero Group’s 2023 annual report, it states “Hero markets
27 baby food in the US and Canada under the brand names Beech-Nut and Baby Gourmet.” Beech-Nut
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1 branded baby foods aim at infants 4+ months up to 12+ months and include a variety of cereals,
2 “jars,” and “pouches” for these age groups. At all relevant times, Beech-Nut has conducted business
3 and derived substantial revenue from its manufacturing, advertising, distributing, selling, and
4 marketing of Baby Foods within the state of New York.
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6 15. Defendant HERO A.G., aka Hero Group (“Hero Group”) is a citizen of Switzerland,
7 with its principal place of business located in Karl Roth-Strasse 8, 5600, Lenzburg, Switzerland.
8 Hero Group sells baby food through its subsidiary, Beech-Nut, which it controls. For example, Hero
9 Group made executive-level decisions for Beech-Nut concerning the acquisition of testing machines
10 need to test baby foods for heavy metal. Hero Group, thus, has been directly involved in the tortious
11 conduct in the United States and its various states that give rise to these lawsuits. At all relevant
12 times, Hero Group conducted business and derived substantial revenue through Beech-Nut by
13 manufacturing, advertising, distributing, selling, and marketing baby foods within the state of New
14 York.
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16 16. The relationship between Beech-Nut and Hero Group was formed in 2005. Prior to
17 that, starting in 1998, Beech-Nut was owned and operated by the Milnot Holding Corporation, and
18 prior to that starting in 1989, Beech-Nut was owned and operated by Ralston Purina, and prior that,
19 starting in 1979, Beech-Nut was owned and operated by Defendant Nestlé.
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21 17. For the purposes of this Complaint, allegations related to Beech-Nut apply equally to
22 Hero Group, as each Defendant exercised authority and control over the sale, manufacture, and
23 distribution of Beech-Nut’s Contaminated Baby Foods at issue in this MDL.
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25 18. Defendant GERBER PRODUCTS COMPANY is a citizen of Michigan and Virginia
26 with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209.
27 Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad
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1 categories of “formula”, “baby cereal”, “baby food”, “snacks”, “meals & sides” “beverages” and
2 “organic”. At all relevant times, Gerber has conducted business and derived substantial revenue
3 from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the
4 state of New York. Gerber is a wholly owned subsidiary of and is directly controlled by Nestlé
5 Holdings, Inc.
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7 19. Defendant NESTLÉ HOLDINGS, INC. (“NHI”) is a citizen of Delaware and
8 Virginia with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia
9 22209. According to its December 2023 annual report, “NHI is the holding company for Nestlé
10 S.A.’s principal operating subsidiaries in the United States, which include, among others, Nestlé
11 USA, Inc., Nestlé Purina Petcare Company, and Gerber Products Company.” NHI is a wholly
12 owned subsidiary of Nestlé S.A. (“Nestlé”). Thus, NHI is the holding company for Nestlé that
13 directly controls and operates Gerber – as noted by the sharing of the same address. Indeed, nearly
14 every safety specialist that oversees the heavy metal content of Gerber baby foods, working
15 currently in the internal project “Metallica,” are employed directly by NHI and/or Nestlé S.A. At all
16 relevant times, NHI conducted business and derived substantial revenue through Gerber by
17 manufacturing, advertising, distributing, selling, and marketing baby foods within the state of New
18 York involved in this litigation.
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20 20. Defendant NESTLÉ S.A. is a citizen of Switzerland, with its principal place of
21 business located at Avenue Nestlé 55, 1800 Vevey, Switzerland. Nestlé is a global food and
22 beverage company with more than 2,000 brands. Nestlé sells baby food under its subsidiary, Gerber,
23 which it directly controls through its wholly owned subsidiary NHI. Employees and scientists at
24 Nestlé trained and set safety standards at Gerber. Indeed, in discovery ongoing in other litigation,
25 Gerber specifically identified scientists at Nestlé to testify on behalf of Gerber regarding the safety
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1 of Gerber's baby food products. Nestlé, thus, has been directly involved in the tortious conduct in
2 the United States and its various states that gives rise to these lawsuits. At all relevant times, Nestlé
3 conducted business and derived substantial revenue through Gerber and/or NHI by manufacturing,
4 advertising, distributing, selling, and marketing baby foods within the state of New York.
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6 21. The relationship between Gerber, NHI, and Nestlé was formed in 2007. Prior to that,
7 starting in 1994, Gerber was owned and operated by Novartis, one of the largest pharmaceutical
8 companies in the world. However, in 2007, Gerber was sold to Nestlé for \$5.5 billion.
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10 22. For the purposes of this Complaint, unless specifically stated otherwise, NHI and
11 Nestlé shall be collectively referred to as "Nestlé." Further, allegations related to Gerber apply
12 equally to NHI and Nestlé, as each Defendant exercised authority and control over the sale,
13 manufacture, and distribution of Gerber's Contaminated Baby Foods at issue in this MDL.
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15 23. Defendant WALMART, INC. ("Walmart") is a citizen of Delaware and Arkansas
16 with its principal place of business located at 702 S.W. 8th St. Bentonville, AK 72716. Walmart
17 sells Baby Foods under the private label brand "Parent's Choice." The foods are manufactured by
18 co-manufacturers, but are sold under Walmart's private label using Walmart's name. Walmart's
19 Parent's Choice offers a wide selection of baby foods ranging from "sweet potatoes & corn" to
20 "toddler cookies" and "yogurt bites." At all relevant times, Walmart has conducted business and
21 derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing
22 of Baby Foods within the state of New York.
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24 **JURISDICTION AND VENUE**

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26 24. As an MDL transferee court, this Court has subject matter and personal jurisdiction
27 to the same extent as the respective transferee courts do. In general federal courts have subject
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1 matter jurisdiction over each of the actions under 28 U.S.C. § 1332(d) because Plaintiffs are citizens
2 of states other than states where Defendants are citizens. In addition, each Plaintiff seeks damages in
3 excess of \$75,000, exclusive of interest and costs.

4
5 25. This Court has personal jurisdiction over Defendants because their significant
6 contacts related to this litigation in each State makes personal jurisdiction proper over any of them.

7 26. In particular, this Court has personal jurisdiction over Defendants for cases filed in
8 this District insofar as Defendants are authorized and licensed to conduct business in the State of
9 California, maintain and carry on systematic and continuous contacts in this judicial district,
10 regularly transact business within this judicial district, and regularly avail themselves of the benefits
11 of this judicial district.

12
13 27. Additionally, Defendants caused tortious injury by acts and omissions in this judicial
14 district and caused tortious injury in this district by acts and omissions outside this district while
15 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
16 substantial revenue from goods used or consumed and services rendered in this judicial district.

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18 28. Venue is proper in this District for pretrial purposed for all cases because this
19 litigation was centralized here under 28 U.S.C. § 1407.

20 29. Venue is proper in this District under 28 U.S.C. § 1391(a) for cased filed here
21 because a substantial part of the events and omissions giving rise to those Plaintiff' claims occurred
22 in this district.

23
24 30. Plaintiff files this Complaint pursuant to PTO No. 5, and are to be bound by the
25 rights, protections, and privileges, and obligations of that PTO and other Order of the Court. Further,
26 in accordance with PTO No. 5, Plaintiff hereby designates the United States District Court for the
27 Eastern District of New York as Plaintiff's designated venue ("Original Venue"). Plaintiff makes
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1 this selection based upon one (or more) of the following factors.

2 ☐ Plaintiff currently resides in _____;

3 ☒ Plaintiff purchased and consumed Defendant(s) products in Nassau County, New York.

4 ☐ The Original Venue is a judicial district in which Defendant _____ resides, and all
5 Defendants are residents of the State in which the district is located (28 U.S.C. 1391(b)(1)).

6 ☒ The Original Venue is a judicial district in which a substantial part of the events or
7 omissions giving rise to the claim occurred, specially (28 U.S.C. 1391(b)(2)): Plaintiff
8 purchased and used the subject Contaminated Baby Food Products, as well as the general
9 location of the Plaintiff's diagnosis and treatment.

10 ☐ There is no district in which an action may otherwise be brought under 28 U.S.C. 1391,
11 and the Original Venue is a judicial district in which Defendant _____ is subject to the
12 Court's personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)),

13 ☐ Other reason (please explain): _____.

14 **FACTUAL ALLEGATIONS**

15 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

16 31. In October 2019, an alliance of nonprofit organizations, scientists and donors named
17 "Happy Babies Bright Futures" ("HBBF"), dedicated to designing and implementing "outcomes-
18 based programs to measurably reduce babies' exposures to toxic chemicals, "published a report
19 investigating the presence of Toxic Heavy Metals in baby foods. The HBBF Report tested 168
20 different baby foods sold on the U.S. market and concluded that "[n]inety-five percent of baby foods
21 tested were contaminated with one or more of four toxic heavy metals- arsenic, lead, cadmium, and
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mercury. All but nine of the 168 baby foods contained at least one metal; most contained more than one.” Specifically, the HBBF report identified “puffs and other snacks made with rice flour,” “[t]eething biscuits and rice rusks,” “infant rice cereal,” “apple, pear, grape, and other fruit juices,” and “carrots and sweet potatoes” manufactured by the Defendants as particularly high in Toxic Heavy Metals.

32. The results of the HBBF report were consistent with that of the U.S. Food and Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or 88 percent of baby foods tested by HBBF- 148 of 168 baby foods- FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.” The HBBF’s findings were by no means an outlier. Eight months prior to publication of the HBBF report, a study conducted by scientists at the University of Miami and the Clean Label Project “examined lead...concentrations in a large convenience sample of US baby foods.” The study detected lead in 37% of samples.

33. Moreover, earlier in 2017, HBBF commissioned a study to evaluate the presence of arsenic in infant rice cereal products sold in the U.S., and the potential risks to children’s neurodevelopment posed by contamination levels. The findings were concerning. The authors concluded that “exposures to arsenic from infant rice cereal approach or exceed existing health-based limits for arsenic levels...leaving little room for additional exposures from other dietary sources, such as snacks, apple juice, and drinking water... Our analyses of arsenic exposures from infant rice cereal during the first year of life suggest that these exposures are not insignificant, and may place infants at risk for adverse health effects.”

II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods Manufactured and/or Sold by Defendants, Sparking National Outrage

34. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of

1 Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and
2 Reform, published two reports detailing its findings that Toxic Heavy Metals—including lead,
3 arsenic, mercury, and cadmium—were present in “significant levels” in numerous commercial Baby
4 Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone), and Beech-Nut—
5 produced internal testing policies, test results for ingredients and finished products, and
6 documentation about what the companies did with ingredients and/or finished products that
7 exceeded their internal testing limits. Three companies—Plum (Campbell), Walmart, and Sprout—
8 initially refused to cooperate.
9

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11 35. Congress reported that the data submitted by the companies unequivocally revealed
12 that a substantial number of Defendants' finished products and/or ingredients used to manufacture
13 the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic, mercury, and cadmium.
14 And, where the Defendants did set internal limits for the amount of metals they allowed in their
15 foods, Defendants routinely flouted their own limits and sold foods that consistently tested above
16 their limits. Congress found the following:
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18 36. **Beech-Nut.** Beech-Nut, along with Hero Group, used ingredients after they tested as
19 high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb
20 arsenic to address product characteristics such as “crumb softness.” On June 8, 2021, four months
21 following the Congressional findings, Beech-Nut issued a voluntary recall of its infant single grain
22 rice cereal and exited the rice cereal market completely. In its recall, Beech-Nut confirmed that its
23 products exceed regulatory arsenic limits. And, Beech-Nut used ingredients containing as much as
24 886.9 ppb lead, as well as 483 products that contained over 5 ppb lead, 89 that contained over 15 ppb
25 lead, and 57 that contained over 20 ppb lead. In its follow up Report in September 2021 Congress
26 specifically focused on Defendants Beech-Nut and Gerber's infant rice cereals. Congress noted that
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1 Beech-Nut rice cereal tested up to 125 ppb inorganic arsenic and averaged 85.47 ppb inorganic
2 arsenic. Beech-Nut's practice of testing ingredients, rather than finished products, for toxic heavy
3 metals appears to have contributed to its failure to detect the dangerous inorganic arsenic levels in its
4 recalled products. Lastly, Beech-Nut does not even test for mercury in baby food.

5
6 37. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67 batches of
7 rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used ingredients that
8 tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead. Nestlé and
9 Gerber rarely test for mercury in their baby foods. In the September 2021 follow-up Congressional
10 report, it was revealed that Nestlé and Gerber's rice cereal tested up to 116 ppb inorganic arsenic,
11 and their average rice cereal product contained 87.43 ppb inorganic arsenic, which is even higher
12 than the amount contained in Beech-Nut's average rice cereal product. While Beech-Nut recalled
13 some of its products and completely discontinued sales of its rice cereal, Nestlé and Gerber have
14 taken no such actions to protect children.

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17 38. **Walmart.** Walmart refused to cooperate with the House Subcommittee's
18 investigation into its baby food products, and as such, the Subcommittee was "greatly concerned"
19 that Walmart "might be obscuring the presence of higher levels of toxic metals in their baby food
20 products." The Subcommittee noted that independent data from HBBF Report confirmed that
21 Walmart's baby foods are indeed tainted. For example, the HBBF Report observed that one of
22 Walmart's products contained 56.1 ppb total arsenic, and 26.1 ppb cadmium. Another product
23 contained 108 ppb total arsenic, 66 ppb inorganic arsenic, 26.9 ppb lead, and 2.05 ppb mercury.

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25 39. Following the publication of the Subcommittee Report, Walmart provided documents
26 to the Subcommittee. On September 29, 2021, the House Subcommittee released a subsequent report
27 entitled "New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby
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1 Foods.” The Subcommittee report addendum described the documents from Walmart as “revealing a
2 concerning lack of attention to toxic heavy metal levels in baby food and an abandonment of its
3 previously more protective standards.” Walmart does not appear to conduct any testing of its baby
4 food products. Walmart sets maximum arsenic and lead levels and asks the manufacturer of its
5 private label to self-certify, but Walmart does not appear to collect any test data or check the
6 accuracy of those certifications. Walmart does not require any mercury or cadmium testing and does
7 not set any standards for mercury or cadmium levels.
8

9 40. The metal concentrations discussed above and further below surpass the limits
10 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the presence of
11 Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic
12 in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To
13 the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods
14 exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels
15 (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the
16 allowable level of mercury in drinking water at 2 ppb. However, these limits were created in
17 reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the
18 Defendants’ baby foods and their ingredients are multiple folds greater than the permitted metal
19 levels. Moreover, compounding these troubling findings, the Defendants set internal limits for the
20 presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then
21 routinely failed to abide by those inadequate standards, as discussed below.
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23 41. As Congress observed, the Defendants have willfully sold—and continue to sell—
24 contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of
25 Toxic Heavy Metals in their products.
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1 **III. Defendants Engaged in a Pattern and Practice of Selling Contaminated Baby Foods and**
2 **Failed to Reduce Metal Levels**

3 42. Several factors drive the Toxic Heavy Metal contamination of Defendants' baby
4 foods, all of which are within Defendants' control.

5 43. *First*, at various times, all Defendants sourced ingredients that contained elevated
6 levels of Toxic Heavy Metals. These ingredients were then used to manufacture the baby foods
7 consumed by Plaintiff, thereby exposing Plaintiff to Toxic Heavy Metals that cause brain damage
8 and other neurodevelopmental harm. One way for Defendants to "deal" with this issue involved
9 relegating any testing of Toxic Heavy Metals to suppliers and co-manufacturers, who were required
10 to certify that Toxic Heavy Metals were below a certain threshold. Defendants would audit those
11 results, discover that the reported certifications were false or inaccurate, and then take no action to
12 stop the use of those ingredients or finished products.
13

14 44. *Second*, some Defendants implemented dangerously high internal limits
15 ("specifications" or "specs") for the maximum level of Toxic Heavy Metals that Defendants allowed
16 in the baby foods. Such high limits—untethered to any consideration of the low levels at which
17 metals are capable of damaging babies' brains—allowed Defendants to source and use ingredients
18 that contained elevated Toxic Heavy Metals to manufacture the baby foods consumed by Plaintiff. In
19 the highly competitive and lucrative baby food market, using contaminated ingredients allows each
20 Defendant to retain greater market share.
21

22 45. *Third*, some Defendants failed to implement any internal specifications for the
23 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not looking
24 at the issue, certain highly contaminated ingredients and finished products were allowed to be used
25 and sold to consumers. This would happen notwithstanding the Defendants' specific knowledge of
26 the risk of Toxic Heavy Metals and their presence in ingredients and finished products.
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1 46. *Fourth*, Defendants did not routinely adhere to their own internal metal specifications
2 or standards, allowing contaminated ingredients and finished products to be released as “exceptional
3 releases” or other simpler terminology. This resulted in ingredients being used and baby foods
4 manufactured and sold that contained levels of Toxic Heavy Metals far higher than what was
5 internally set by Defendants. In other instances, Defendants would test products that had been put
6 on the market after-the-fact, learn about the products containing extremely high levels of Toxic
7 Heavy Metals, and then take no action to recall the product or warn consumers about the issue.

8
9 47. *Fifth*, upon information and belief, Defendants’ manufacturing practices also
10 contributed to contamination. For example, the water used at some of the facilities where the baby
11 foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the finished
12 baby food product sold for consumption by babies.

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14 48. **Beech-Nut.** Beech-Nut and Hero Group did not test their finished baby foods for
15 heavy metals, only ingredients. And, Beech-Nut and Hero Group regularly accepted ingredients
16 testing far higher than its internal limits for Toxic Heavy Metals. They justified such deviations as
17 “exceptional releases.” For example, Beech-Nut and Hero Group “exceptionally released” 160,000
18 pounds of sweet potatoes for their baby food products notwithstanding the ingredient testing twice as
19 high as Beech-Nut’s internal heavy metal limit for lead.

20
21 49. Moreover, Beech-Nut and Hero Group did not adequately test their ingredients for
22 heavy metals by limiting ingredient lots and ingredient quantities that were subject to metal testing.
23 For example, if a supplier supplied ingredients below a certain amount, they would not test anything
24 and simply use the ingredient in the finished product. Furthermore, in deciding to violate their own
25 internal limits, Beech-Nut and Hero Group took advantage of the fact that the FDA does not
26 routinely test baby foods for Toxic Heavy Metals.
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1 50. Upon information and belief, Beech-Nut and Hero Group went so far as to manipulate
2 their testing practices by continually re-testing ingredients that tested above their internal specs until
3 they obtained a result that was at or below their internal specs, knowing full well that the ingredient
4 was nonetheless contaminated.
5

6 51. Beech-Nut and Hero Group's internal specifications varied wildly by ingredient, with
7 Beech-Nut allowing very high levels of Toxic Heavy Metals for certain ingredients, and insisting on
8 lower levels for others. Thus, certain products like rice flour, were allowed to have very high levels
9 of metals like arsenic and lead, even in products that were 90% or more rice. Beech-Nut and Hero
10 Group did this because there were no regulations governing Toxic Heavy Metal in baby food and,
11 therefore, to remain competitive in the baby food marketplace, Beech-Nut used contaminated
12 ingredients because they were readily available.
13

14 52. **Gerber.** Gerber, NHI, and Nestlé tested ingredients and, occasionally, finished
15 products. However, while Gerber, NHI, and Nestlé were the only Defendants to test both ingredients
16 and finished products with any regularity, they set high heavy metal limits that rendered their food
17 unsafe. For baby foods generally, between 2012 and 2019, Gerber, NHI, and Nestlé set a limit of 40
18 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant rice cereal, between 2012 and
19 2017, Gerber, NHI, and Nestlé set a lead limit of 100 ppb, with a "target" of 50 ppb in 2016 and
20 2017. Between 2018 and 2019, Gerber, NHI, and Nestlé set a lead limit for 50 ppb. For arsenic in
21 rice cereal, between 2012 and 2015, Gerber, NHI, and Nestlé did not have a limit, merely a target of
22 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber, NHI,
23 and Nestlé increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at 100
24 ppb for other cereals). For snack foods, Gerber, NHI, and Nestlé had a lead limit of 150 ppb
25 between 2012 and 2014. It was reduced to 100 ppb in 2016 and 2017, and then went down to 50 ppb
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1 in 2018 and 2019. There was no limit for arsenic in snack food prior 2016, just a “target” of 100
2 ppb. Then a 100-ppb arsenic limit was set starting in 2016. For both infant cereal and snacks,
3 Gerber, NHI, and Nestlé imposed a 30-ppb limit for mercury in infant cereal between 2012 and
4 2016, and reduced it to 10 ppb from 2017 onward. With these exceptionally high limits, Gerber,
5 NHI, and Nestlé sold baby foods that were dangerous for infant consumption. They did this
6 knowingly.

8 53. Gerber, NHI, and Nestlé would also audit and re-test Toxic Heavy Metal results
9 submitted by suppliers, and find that the certification from suppliers were incorrect or false. Gerber,
10 NHI, and Nestlé would nonetheless use the certified results and release products despite the
11 ingredients not meeting specifications or being safe for infant consumption.

13 54. Gerber, NHI, and Nestlé often used high-arsenic ingredients, for example, using 67
14 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Gerber, NHI, and
15 Nestlé regularly sold baby food products testing over 100 ppb arsenic, at times reaching 116 ppb,
16 and their average rice cereal product contained 87.43 ppb inorganic arsenic. Indeed, this is why
17 Congress noted that “Gerber’s organic rice cereal is dangerous...” In other instances, Gerber
18 permitted as much as 300 ppb of arsenic in the rice flour ingredient used to manufacture its U.S.
19 baby foods, notwithstanding the fact that Gerber often implemented stricter standards for baby foods
20 sold in other countries.

23 55. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber, NHI,
24 and Nestlé used ingredients that tested as high as 48 ppb lead and used many ingredients containing
25 over 20 ppb lead. Furthermore, Gerber, NHI, and Nestlé sold baby food products testing at and/or
26 above 50 ppb of lead. Indeed, Gerber, NHI, and Nestlé have historically permitted as much as 150
27 ppb lead in their baby food products. Although Gerber, NHI, and Nestlé were fully aware that it was
28

1 very feasible to source lower-lead ingredients, they proceeded to use high-lead ingredients in their
2 baby foods. Gerber, NHI, and Nestlé rarely test for mercury in their baby foods. This is
3 notwithstanding the fact that mercury is known to contaminate ingredients such as rice and poses a
4 severe risk to babies' brain development.

5
6 56. The February 4, 2021 Congressional Report found Gerber carrots tested for cadmium
7 at levels above 5 ppb, with some containing more than 87 ppb of cadmium. These are exceptionally
8 high levels.

9
10 57. Moreover, compounding these troubling findings, Gerber, NHI, and Nestlé
11 historically only tested certain ingredients of its baby food products and only occasionally tested the
12 finished products consumed by babies. It was not until recently that Gerber, NHI, and Nestlé started
13 to implement finished product testing on a more regular basis.

14
15 58. Gerber, NHI, and Nestlé have known since at least the 1990s that inorganic arsenic
16 was neurotoxic and caused developmental issues. Despite this knowledge, in 2012, when Gerber's
17 infant rice cereal was on the front page of a Consumer Report article on arsenic, a Gerber
18 spokesperson told the public that arsenic in baby food posed no health risk.

19
20 59. **Walmart.** Walmart sold baby food under a "private" brand called "Parent's Choice",
21 which was manufactured by a different supplier but branded, promoted, and sold as a Walmart
22 product. Walmart did not test it for Toxic Heavy Metals whatsoever. Instead, Walmart required
23 certain specifications be met for the products provided by its suppliers, which included some limits
24 of heavy metals. These specifications were not enforced in any way. Walmart did not require the
25 submission of testing from suppliers, nor did it do any of its own testing.

26
27 60. The only efforts to police Toxic Heavy Metals in their Parent's Choice baby food
28 involved generic specifications for lead and arsenic—there were no other specifications or limits for

other Toxic Heavy Metals—which for most baby food products resulted in there being no limits. The following chart reflects Walmart’s Toxic Heavy Metal specifications prior to December 2018.

Type of Food	Lead	Arsenic	Mercury	Cadmium	Aluminum
Dry baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Dry baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Wet baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Wet baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Yogurt baby food products	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

61. In December 2018, Walmart changed its specification to 100 ppb of inorganic arsenic for all dry baby foods, making the products even less safe. Thus, for the vast majority of Walmart’s baby food products, there was never a limit for any Toxic Heavy Metals.

IV. Defendants Abandon Efforts to Reduce Metal Levels in Baby Foods

62. In 2019, as concerns grew over contamination of certain baby foods on the U.S. market, a consortium of the Defendants comprised of Beech-Nut, Plum/Campbell, Gerber, Hain, Nurture, and Sprout, as well as certain interested third party groups such as the Environmental Defense Fund (“EDF”) and HBBF, were formed with the intention “of reducing heavy metals in young children’s food.”

63. The consortium was named the Baby Food Council (“BFC”). The BFC involved the sharing of common testing data on the levels of metal contamination of Defendants’ baby foods, a grant to Cornell University to further study the issue, and a proposed “voluntary Baby Food Standard to limit the amounts of heavy metals in baby food.” The BFC specifically recognized the risk of neurodevelopmental harm caused by Toxic Heavy Metals to the developing brain of infants and that there were no safe levels of exposure.

1 64. The Baby Food Standard “would have provided companies with a common
2 framework for progressively reducing contaminants by regularly testing products and improving
3 management practices, and for being transparent with consumers about the safety of their products.”

4
5 65. After several years of negotiations and discussions, including a proposed system for
6 testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food companies,
7 however, rejected the proposal outright. Participation in the BFC was little more than a façade—
8 they had no intention of self-regulating their products as it related to Toxic Heavy Metals.

9
10 66. This led EDF and HBBF to leave the BFC in protest in 2021. They explained their
11 departure publicly, noting that Defendants “all decided to backpedal on this project—even though
12 the standard was designed to protect babies’ brain development” and provide adequate notice to
13 consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling. EDF explained:

14 EDF cofounded the Council because we believed there was a shared commitment to
15 reduce levels of lead, arsenic and cadmium in baby food products to better protect
16 children’s developing brains from these toxins... Unfortunately, the companies chose
17 to cease the Council’s development of a voluntary Baby Food Standard that it had
18 begun in late 2020. The Standard would have provided companies with a common
19 framework for progressively reducing contaminants by regularly testing products and
20 improving management practices, and for being transparent with consumers about the
21 safety of their products. Negotiations failed to provide an alternative approach that
22 EDF felt was sufficient to drive down levels of lead, arsenic and cadmium in baby
23 food.”

24 67. HBBF explained:

25 Healthy Babies Bright Futures is focused on tangibly reducing neurotoxic exposures
26 to babies. The baby food companies’ refusal to jointly set limits for heavy metals in
27 baby food has shown that the Council will no longer be the powerful mechanism for
28 this important work that the initial plans had promised. The baby food companies’
decision to stop progress on a voluntary standard for heavy metals in baby food is a
disappointment...What started as dedication has turned into delay and intention has
become inaction. So HBBF has decided to put our effort into other initiatives that
will move the needle on this important issue.

68. In short, the Defendants opted to continue “self-regulating,” the same self-regulation which exposed—and continued to expose—Plaintiff to Toxic Heavy Metals in Defendants’ baby foods.

V. The Dangers of Toxic Heavy Metals and Metal Exposure Through Consumption of Baby Foods

69. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for children. The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may build up in biological systems and become a significant health hazard.” Indeed, the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), mercury (third), and cadmium (seventh).

70. The threat presented by Toxic Heavy Metals to children’s health is widely shared by the global regulatory and scientific community. For example, the FDA has set an Interim Reference Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products. That is the amount of lead exposure at or above which the agency considers associated with adverse neurodevelopmental effects in babies. The FDA, in its guidance documents for inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the neurodevelopment of infants.

Even low lead exposure can harm children’s health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects...Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time...Even though no safe level of lead exposure has yet been

identified for children's health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that *such adverse effects of lead consistently occur at a blood lead level associated with FDA's IRL for children.* (emphasis added).

71. As one recent study observed, “[t]he implications of heavy metals with regards to children’s health have been noted to be more severe compared to adults. The elements’ harmful consequences on children health include mental retardation, neurocognitive disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given to heavy metals because of their high toxicity potential, widespread use, and prevalence.” Children and, even more so, babies have higher exposure to metals compared to adults because they consume more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.

72. The mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults. For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”

73. Thus, “the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth.” In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations

74. It is well-known that exposure to Toxic Heavy Metals in early life can interfere with

1 neurodevelopment at exceedingly low levels of exposure. And, one of the ways in which such
2 interference with neurodevelopment can present in a child is in the form of the neurodevelopmental
3 disorders ASD and ADHD. As the U.S. Centers for Disease Control observed in its 2020
4 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following neurobehavioral effects in children
5 have been associated with [lead]: “Altered mood and behaviors that may contribute to learning
6 deficits, including *attention deficits, hyperactivity, autistic behaviors*, conduct disorders, and
7 delinquency.” (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure
8 to heavy metals...may be linked to autism spectrum disorder.”
9

10
11 75. Such conclusions have likewise been reached by a consortium of the country’s
12 leading epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals such as
13 lead and mercury are “prime examples of toxic chemicals that can contribute to learning, behavioral,
14 or intellectual impairment, as well as specific neurodevelopmental disorders such as ADHD or
15 autism spectrum disorder.”
16

17 76. Multiple studies, reviews, and meta-analyses conducted throughout various parts of
18 the world over the last decade have consistently observed that early life exposure to heavy metals
19 can cause brain injury and, specifically, brain injury which manifests as ASD.
20

21 77. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,
22 respectively, observed consistent associations between exposure to arsenic, cadmium, and mercury
23 and ASD in children; with the authors in all three studies recommending – based on the data – that
24 exposure to such metals in children be reduced as much as possible, and one of the study authors
25 specifically concluding that “Results of the current meta-analysis revealed that mercury is an
26 important causal factor in the etiology of ASD.”
27

28 78. In a recent 2017 NIH-funded prospective observational study, the authors examined

1 the risk of ASD outcome in twins based on their respective body burden of lead. The study
2 concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency)
3 of multiple metals during critical developmental windows is associated with ASD, and suggests a
4 role for elemental dysregulation in the etiology of ASD.”

5
6 79. Similarly, a large, prospective study from 2016 in Korean school children observed
7 that low levels of lead exposure in early life are associated with autism, the authors specifically
8 concluding: “even low blood lead concentrations...are associated with more autistic behaviors...
9 underscoring the need for continued efforts to reduce lead exposure.”

10
11 80. Studies have repeatedly observed strong associations between exposure to cadmium
12 and aluminum and neurodevelopmental disorders such as ASD, as observed by a recent study:
13 “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been associated with
14 neurodevelopmental disorders including autism spectrum disorder (ASD).” For example, a study
15 from 2014 evaluated the body burden of lead, cadmium, and arsenic in children with autism
16 compared to controls and noted that, in addition to lead and arsenic, “our study demonstrated
17 elevation in the levels of...cadmium...in a child with autism,” while an earlier study noted that
18 “autism may be associated with significant alterations of some rare element concentrations,
19 including Cd...” Such results have been confirmed by meta-analyses which “*show significant*
20 *associations* between ASD and the metals Al [and] Cd.” And, such earlier data is further supported
21 by recent research, with a 2023 systematic review and meta-analysis concluding that “compared with
22 the healthy control group, the ASD group had higher concentrations of Cd, Pb, arsenic, and Hg.
23 These 4 heavy metals play different roles in the occurrence and progression of ASD.”

24
25 81. Repeated associations between early life Toxic Heavy Metal exposure and ASD have
26 also been observed during the pre-natal timeframe, lending further strength to the findings of post-
27
28

1 natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively
2 assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk.
3 The study concluded that “[r]esults from the present study show several associations between levels
4 of metals and elements during gestation and ASD and ADHD in children. The most notable ones
5 involved arsenic...mercury...and lead. Our results suggest that even population levels of these
6 compounds may have negative impacts on neurodevelopment.”

8 82. Similarly, in a study by the research group assessing the New Hampshire Birth
9 Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of
10 pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late
11 pregnancy may be neurodevelopmentally harmful.”

13 83. Such results have been replicated in studies throughout the world, including China,
14 Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of
15 autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this study are
16 consistent with numerous previous studies, supporting an important role for heavy metal exposure,
17 particularly mercury, in the etiology of ASD.” Indeed, a 2015 Egyptian study noted
18 “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a
19 *casual* role in autism.” (emphasis added).

21 84. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly
22 associated with the development of ADHD in children, as demonstrated by numerous studies.

24 85. No fewer than four large meta-analyses, conducted in four different continents
25 (North America, America, South America, Europe and Asia), and some employing a cross-sectional
26 design, have observed a consistent association between various metals and ADHD in children.
27 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies
28

1 allowed us to establish that there is an association between lead and ADHD and that even *low levels*
2 *of lead raise the risk.*” (emphasis added).

3 86. The findings from the meta-analyses have been replicated in several Chinese studies
4 from 2006, 2014, and 2018, respectively. Notably, the authors of the 2014 Chinese study observed
5 that “[e]xposure to lead even at low levels correlates with attention-deficit/hyperactivity disorder
6 (ADHD). However, lead-contaminated environments are often *contaminated with other heavy*
7 *metals that could exacerbate lead-induced ADHD.*” (emphasis added). This is particularly
8 relevant—and disturbing—as children who consumed Defendants’ baby foods were repeatedly
9 exposed to a cocktail of Toxic Heavy Metals that, synergistically, further increased their risk of
10 developing ADHD.
11

12 87. Moreover, studies have observed a dose-response relationship between exposure to
13 Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.* Another
14 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to examine the
15 association between exposure to arsenic and ADHD. After adjusting for potential confounders, the
16 authors observed a dose-response relationship between urine arsenic levels and inattention and
17 impulsivity scores, concluding that “[urine arsenic] levels were associated with impaired
18 attention/cognitive function, *even at levels considered safe.* These results provide additional
19 evidence that postnatal arsenic exposure impairs neurological function in children.” (emphasis
20 added.)
21

22 88. The fact that such results, and many more, have been observed in multiple studies,
23 conducted by different researchers, at different times, in different parts of the world, in children of
24 multiple ages, utilizing different study methods (prospective, case-control and cross-sectional
25 epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine),
26
27
28

1 strongly supports a causal relationship between exposure to Toxic Heavy Metals and the
2 development of ASD and ADHD in children.

3 **B. Defendants' Baby Foods Contain Toxic Heavy Metals Capable of Interfering with**
4 **Early Neurodevelopment**

5 89. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting damage to
6 the developing brain at extremely low doses. And, upon information and belief, Defendants
7 manufactured and sold baby foods containing Toxic Heavy Metals that can, under certain
8 circumstances (based upon the genetic susceptibilities, medical history, and other factors of the
9 exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions such as ASD
10 and ADHD.

11
12 90. As an initial matter, the study commissioned by HBBF and discussed above
13 specifically evaluated the propensity for arsenic exposure through consumption of infant rice cereal
14 to impact early life neurodevelopment. Following analyses of the levels of arsenic exposure from
15 consumption of infant rice cereal, the authors concluded "that high consumers of infant rice cereal
16 (i.e., infants eating three servings per day) eating products currently on the U.S. market would have a
17 daily arsenic intake of 0.35-0.67 $\mu\text{g/kg bw/day}$...per the Tsuji et al. (2015) lower-bound estimate for
18 an RFD for the neurodevelopmental effects of arsenic (0.4 $\mu\text{g/kg bw/day}$), high consumers of infant
19 rice cereal may also be at risk for this endpoint. Even in average consumers of infant rice cereal
20 (i.e., one serving per day), our estimates of arsenic intakes (0.15 to 0.29 $\mu\text{g/kg bw/day}$) leave little
21 room for exposures to arsenic from other sources." Thus, consumption of Defendants' baby foods,
22 including but not limited to infant rice cereal and rice-based snack baby food products manufactured
23 and sold by Defendants can expose babies to levels of arsenic above that associated with
24 neurodevelopmental harm in the scientific literature.

25
26 91. Defendants manufactured and sold baby food products that, with just a couple of
27
28

1 servings, are capable of exposing a baby to lead levels at or above the 2.2 ug/day considered by the
2 FDA to be associated with neurodevelopmental harm. Each source of lead exposure is cumulative—
3 making any detectable amount of Toxic Heavy Metal in baby food a contributing factor to potential
4 neurodevelopmental harm.
5

6 92. Similarly, upon information and belief, Defendant Hain was aware of the neurotoxic
7 propensities of lead, arsenic, and mercury at low levels, but proceeded to manufacture and sell Baby
8 Foods containing arsenic and lead levels that, upon information and belief, Hain considered as
9 capable of inflicting neurodevelopmental harm.
10

11 **VI. Defendants Knowingly Sold Baby Foods Containing Toxic Heavy Metals and Knew or**
12 **Should Have Known of the Risks of Such Exposures in Children and Thus Breeched**
13 **their Duty of Care in Selling Contaminated Baby Foods**

14 93. During the time that Defendants manufactured and sold baby foods in the United
15 States, the weight of evidence showed that Defendants' baby foods exposed babies and children to
16 Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

17 94. As discussed above, both independent testing, the Defendants' internal evaluations of
18 their baby foods, and the Defendants' representations and disclosures to Congress and the FDA
19 reveal the presence of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or
20 should have known that their baby foods contain Toxic Heavy Metals with an attendant risk of
21 causing neurodevelopmental harm.
22

23 95. Indeed, independent testing performed in early 2019 demonstrated elevated amounts
24 of such Toxic Heavy Metals in Baby Food products on the U.S. market, and the HBBF Report
25 further confirmed such contamination of Defendants' baby foods. And, as the Congressional
26 investigation found, the Defendants continued to sell their baby foods even after testing of both
27 ingredients and finished products revealed the presence of Toxic Heavy Metals.
28

1 96. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—
2 particularly as it relates to adverse effects on the neurodevelopment of children—have been well
3 known for decades. Defendants, as manufacturers and sellers of baby foods, are held to the standard
4 of experts and responsible for keeping abreast of the latest scientific developments related are held to
5 the dangers of contaminants in their products. Defendants failed to take action to protect vulnerable
6 children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk
7 of brain injury which can manifest as neurodevelopmental disorders such as ASD, ADHD, and
8 related *sequelae*.
9

10 97. To be clear, the Defendants are able to manufacture baby foods that do not pose such
11 a dangerous risk to the health of infants and children by using alternative ingredients, not adding
12 certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients
13 from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of
14 the presence of Toxic Heavy Metals in their Baby Foods.
15

16
17 **VII. Defendants' Baby Food Products Were Defective Due to Insufficient Warnings,**
18 **Manufacturing Defects, and/or Design Defects to the Extent the Baby Food Products**
19 **Contained Detectable Levels of Toxic Heavy Metal**

20 98. All of Defendants' baby food products that contained detectable levels of Toxic
21 Heavy Metals (or constituted finished products wherein the ingredients contained detectable levels
22 of Toxic Heavy Metals), assuming state of the art analytical testing, were defective as it relates to
23 warnings because no Defendant has ever warned about the presence of Toxic Heavy Metals in their
24 baby foods. Because discovery is ongoing, a complete list of Defendants' specific baby foods that
25 contained detectable levels of Toxic Heavy Metals is not known at this time. Based on publicly
26 available testing data, including data reported by HBBF and Congress, the vast majority of
27 Defendants' products contain detectable levels of Toxic Heavy Metals in them, rendering them each
28

1 defective as it relates to warnings. Attached as Appendix A to this Complaint is a list of the
2 Defendants' products now known to be defective. This list, however, is not comprehensive and
3 shall be amended as discovery is obtained.

4
5 99. Defendants' baby food products are also defective as manufactured, as they contain
6 detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic Heavy Metals
7 do not provide any nutritional or therapeutic value to infants or fully-grown humans. They are only
8 poisonous to neurodevelopment. None of these baby food products, by design, should contain Toxic
9 Heavy Metals in them and, thus, to the extent the products contain detectable levels of Toxic Heavy
10 Metals in them, those are manufacturing defects. Based on publicly available data, most of
11 Defendants' baby food products contain some detectable levels of Toxic Heavy Metals in them.
12 However, as the levels of Defendants' baby food products are not known yet, nor do Plaintiff have a
13 complete list of Defendants' baby food products or their formulations—information that will be
14 obtained through discovery—Plaintiff cannot identify each baby food product that contained a
15 manufacturing defect. However, Appendix A is a running list of baby food products sold by
16 Defendants.

17
18 100. If Defendants specifically designed their baby food products to contain Toxic Heavy
19 Metals, meaning their presence was not the product of a manufacturing defect, then the products
20 were defective by design. Toxic Heavy Metals should not be present in foods that are being
21 consumed by infants and products should be designed to not have detectable levels of toxic heavy
22 metal in them. Such designs are easily accomplished, by only using ingredients that contain non-
23 detectable levels of Toxic Heavy Metals and by testing finished products, before release, to ensure
24 they do not contain Toxic Heavy Metals within them. This is possible because there are examples of
25 Defendants' finished products not containing detectable levels of Toxic Heavy Metals—even if, for
26
27
28

1 that same products, there are instances where they did. Thus, Defendants were able to design baby
2 food products to not contain detectable levels of toxic heavy metals, and to the extent that each
3 Defendants' design contemplated there being detectable levels of Toxic Heavy Metals in baby food,
4 the design, itself, was defective. Because Plaintiff does not know the Defendants' intended design
5 for their baby food products—as there has been no discovery obtained to date concerning product
6 formulation, product/ingredient specifications, and testing methodologies/capabilities—Plaintiff
7 cannot specify which baby food products were defectively designed versus which ones were not.
8 That said, Appendix A, a running list of the Defendants' baby food products that, with further
9 discovery, may yield information that will allow Plaintiff to identify whether the product was
10 defectively designed.

13 101. Whether the Defendants' products were defective due to inadequate warnings,
14 manufacturing errors, or by design, the existing publicly available evidence indicates that
15 consumption of Defendants' baby food products can expose infants to Toxic Heavy Metals, and that
16 depending on specific milieu of products consumed by each Plaintiff and each Plaintiff's specific
17 susceptibility and circumstances, Defendants' baby food products contributed to each Plaintiff's
18 Toxic Heavy Metal burden during critical period of infant neurodevelopment. Plaintiff, thus, alleges
19 that this cumulative exposure from Defendants' products to Toxic Heavy Metals, substantially
20 contributed to causing neurodevelopmental harm that manifested as ASD and/or ADHD. Moreover,
21 each Plaintiff alleges that had these baby food products not been defective—by having sufficient
22 warnings, being correctly manufactured, and/or designed properly—each Plaintiff would not have
23 been exposed to levels of Toxic Heavy Metals in Defendants' baby food products that would have
24 contributed to the neurodevelopmental harm that manifested as ASD and/or ADHD.

27 **VIII. Exemplary/Punitive Damages Allegations**

1 102. Defendants’ conduct as alleged herein was done with reckless disregard for human
2 life, oppression, and malice. Defendants’ conduct is particularly reprehensible given that their toxic
3 foods were directed at vulnerable babies—a population group far more susceptible than adults to the
4 neurotoxic dangers of heavy metals.

5
6 103. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
7 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
8 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to
9 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for consumption
10 and go so far as claiming that they adhere to “the strictest standards in the world;” and provide
11 “baby’s food full of nutrition while meeting standards strict enough for tiny tummies,” as well as
12 other statements and representations that hold out their baby foods as safe for consumption by
13 infants. Indeed, each Defendant falsely reassured parents/guardians/caregivers that their baby foods
14 would foster healthy neurodevelopment when consumed even though they knew their baby foods
15 exposed infants’ developing brains to potent neurotoxic heavy metals. In actual fact, as discussed
16 above, Defendants routinely sold Contaminated Baby Foods, regularly flouted their own internal
17 limits of Toxic Heavy Metals and failed to disclose to consumers that their products contained such
18 dangerous contaminants.

19
20
21 104. This was not done by accident or through some justifiable negligence. Rather,
22 Defendants knew they could profit by convincing consumers that their baby foods were healthy and
23 safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals present
24 in the baby foods would limit the amount of money Defendants would make selling the products.
25 Defendants’ object was accomplished not only through a misleading label, but through a
26 comprehensive scheme of selective misleading research and testing, failure to test, false advertising,
27
28

1 and deceptive omissions as more fully alleged throughout this Complaint.

2 Parents/guardians/caregivers were denied the right to make an informed decision about whether to
3 purchase Defendants' baby food for their babies without knowing the full risks attendant to that use.

4 Such conduct was done with conscious disregard of Plaintiff's welfare and rights.
5

6 CAUSE OF ACTION

7 **I. COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

8 105. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
9 if fully stated herein.

10 106. At all relevant times, Defendants engaged in the business of researching, testing,
11 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
12 promoting baby foods, which are defective and unreasonably dangerous to consumers, including
13 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous
14 characteristics of baby foods in the form of the presence of Toxic Heavy Metals. These actions were
15 under the ultimate control and supervision of Defendants. At all relevant times, Defendants
16 registered, researched, manufactured, distributed, marketed, and sold baby foods and aimed at a
17 consumer market.
18

19 107. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
20 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
21 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products
22 to consumers and end users, including Plaintiff, and therefore had a duty to warn about the presence
23 of and risks associated with exposure to Toxic Heavy Metals from the consumption of Contaminated
24 Baby Foods.
25

26 108. At all relevant times, Defendants had a duty to properly test, develop, design,
27 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide
28

1 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not
2 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a
3 continuing duty to warn Plaintiff of dangers associated with exposure to Toxic Heavy Metals from
4 consumption of the Contaminated Baby Foods. Defendants, as a manufacturer, seller, or distributor
5 of food, are held to the knowledge of an expert in the field.
6

7 109. At the time of manufacture, Defendants could have provided the warnings or
8 instructions regarding the full and complete risks of exposure to Toxic Heavy Metals in the
9 Contaminated Baby Foods because they knew or should have known of the unreasonable risks of
10 harm associated with the use of and/or exposure to such toxins.
11

12 110. At all relevant times, Defendants failed and deliberately refused to investigate, study,
13 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
14 those who would foreseeably use or be harmed by exposure to the Toxic Heavy Metals in
15 Defendants' Baby Foods.
16

17 111. Even though Defendants knew or should have known that the presence of Toxic
18 Heavy Metals in Contaminated Baby Foods posed a risk of harm, they failed to exercise reasonable
19 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.
20 The neurotoxic characteristic of Toxic Heavy Metals contained in Defendants' Contaminated Baby
21 Foods, as described above, were known to Defendants, or scientifically knowable to Defendants
22 through appropriate research and testing by known methods, at the time they distributed, supplied, or
23 sold the products, and were not known to end users and consumers, such as Plaintiff. The product
24 warnings for Contaminated Baby Foods in effect during the time period Plaintiff consumed those
25 foods were inadequate, both substantively and graphically, to alert consumers to the presence of and
26 health risks associated with exposure to the Toxic Heavy Metals from Contaminated Baby Food
27
28

1 consumption.

2 112. At all relevant times, Defendants' Contaminated Baby Foods reached the intended
3 consumers, handlers, and users or other persons coming into contact with these products, including
4 Plaintiff, without substantial change in their condition as manufactured, sold, distributed, labeled,
5 and marketed by Defendants.
6

7 113. Plaintiff was exposed to the Toxic Heavy Metals in Defendants' Contaminated Baby
8 Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from
9 consumption of the products and the dangerous characteristics of the toxins.
10

11 114. At all relevant times, Plaintiff was exposed to the Toxic Heavy Metals in the
12 Defendants' Contaminated Baby Foods while consuming the foods for their intended or reasonably
13 foreseeable purposes, without knowledge of their dangerous characteristics.

14 115. Plaintiff could not have reasonably discovered the defects and risks associated with
15 exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the time of
16 Plaintiff consuming those foods. Plaintiff relied upon the skill, superior knowledge, and judgment of
17 Defendants to know about and disclose serious health risks associated with exposure to the toxins in
18 Defendants' products.
19

20 116. The information that Defendants did provide or communicate failed to contain
21 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
22 avoid consuming the products and, in turn, exposure to the Toxic Heavy Metals. Instead,
23 Defendants disseminated information that was inaccurate, false, and misleading, and which failed to
24 communicate accurately or adequately the comparative severity, duration, and extent of the risk of
25 injuries with use of and/or exposure to the Toxic Heavy Metals in the Contaminated Baby Foods;
26 continued to aggressively promote the safety of their products, even after they knew or should have
27
28

1 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise
2 suppressed, through aggressive marketing and promotion, any information or research about the
3 risks and dangers of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
4 Foods.

5
6 117. This alleged failure to warn is not limited to the information contained on
7 Contaminated Baby Foods labeling. The Defendants were able, in accordance with federal law, to
8 comply with relevant New York state law, disclosing the known risks associated with exposure to
9 Heavy Metals in Contaminated Baby Foods through other non-labeling mediums, i.e., promotion,
10 advertisements, public service announcements, and/or public information sources. But the
11 Defendants did not disclose these known risks through any medium. The ability to provide such
12 warnings is not prohibited by any federal law.

13
14 118. Furthermore, Defendants possess a First Amendment Right to make truthful
15 statements about the products they sell, and no law could lawfully restrict that constitutional right.
16 This included making statements about the presence of and risks associated with Toxic Heavy
17 Metals in Contaminated Baby Foods.

18
19 119. Had Defendants provided adequate warnings and instructions and properly disclosed
20 and disseminated the risks associated with exposure to the toxins in their Contaminated Baby Foods,
21 Plaintiff could have avoided the risk of developing injuries and could have obtained or used
22 alternative products. However, as a result of Defendants' concealment of the dangers posed by the
23 Toxic Heavy Metals in their Contaminated Baby Foods, Plaintiff could not have averted their
24 exposures.

25
26 120. Defendants' conduct, as described above, was reckless. Defendants risked the lives
27 of babies and children, including Plaintiff, with knowledge of the safety problems associated with
28

1 Contaminated Baby Foods, and suppressed this knowledge from the general public. Defendants
2 made conscious decisions not to warn or inform the unsuspecting public.

3 121. The Defendants' lack of adequate warnings and instructions accompanying their
4 Contaminated Baby Foods caused Plaintiff's injuries.

5 122. As a direct and proximate result of the Defendants' failure to provide an adequate
6 warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated Baby Foods,
7 Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment,
8 loss of enjoyment of life, economic loss and damages including, but not limited to past and future
9 medical expenses, lost income, and other damages.

10 123. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
11 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
12 such other and further relief as this Court deems just and proper.

13 **II. COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

14 124. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
15 if fully stated herein.

16 125. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
17 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.

18 126. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
19 expected to and did reach Plaintiff without a substantial change in their condition as manufactured,
20 handled, distributed, and sold by Defendants.

21 127. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were used
22 in a manner that was foreseeable and intended by Defendants.

23 128. The Contaminated Baby Foods consumed by Plaintiff were not reasonably safe for
24

1 their intended use and were defective with respect to their manufacture, as described herein, in that
2 Defendants deviated materially from their design and manufacturing specifications and/or such
3 design and manufacture posed an unreasonable risk of harm to Plaintiff. ¹Baby food should not,
4 by design, contain any detectable levels of Toxic Heavy Metals in them. Thus, Defendants'
5 Contaminated Baby Foods contain manufacturing defects.

7 129. The Defendants' Contaminated Baby Foods contained Toxic Heavy Metals because,
8 while in the control and possession of Defendants, they manufactured ingredients and used
9 manufacturing processes that result in the finished product being contaminated with Toxic Heavy
10 Metals. Had Defendants properly manufactured (directly or through co-manufacturers) the baby
11 foods, they would not have contained detectable levels of Toxic Heavy Metals in them and, thus,
12 would not have contained a manufacturing defect.

14 130. Nothing under federal law limited or restricted Defendants from taking action to
15 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.

17 131. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals
18 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental harm
19 that manifested as ASD.

20 132. The exposure to the Toxic Heavy Metals in the Contaminated Baby Foods creates
21 risks to the health and safety of babies that are far more significant than the risks posed by non-
22 Contaminated Baby Food products, and which far outweigh the utility of the Contaminated Baby
23 Foods products because of Defendants' manufacturing defects.

25 133. Defendants have intentionally and recklessly manufactured the Contaminated Baby
26

27
28 ¹ If, through discovery and further litigation, it is discovered that Defendants' baby food products contained detectable levels of Toxic Heavy Metals by design, then Plaintiff will pursue a design defect claim (Count III) in the alternative.

1 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,
2 placing their economic interests above the health and safety of Plaintiff.

3 134. As a direct and proximate result of the Defendants' defective manufacture of the
4 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
5 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
6 but not limited to medical expenses, lost income, and other damages.

7
8 135. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
9 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
10 such other and further relief as this Court deems just and proper.

11
12 **III. COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

13 136. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
14 if fully stated herein.

15 137. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
16 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff. These actions
17 were under the ultimate control and supervision of Defendants.

18
19 138. At all relevant times, Defendants' Baby Food products were designed and labeled in
20 an unsafe, defective, and inherently dangerous manner that was dangerous for use or consumption by
21 infants and babies, including Plaintiff.

22
23 139. Defendants' Contaminated Baby Food products as researched, tested, developed,
24 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
25 were defective in design and formulation in that, when they were placed into the stream of
26 commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an
27 ordinary consumer would contemplate.
28

1 140. Defendants' Contaminated Baby Food products, as researched, tested, developed,
2 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
3 were defective in design and formulation in that, when they left the hands of Defendants, the
4 foreseeable risks exceeded the alleged benefits associated with their design and formulation.
5

6 141. At all relevant times, the Contaminated Baby Food products consumed by Plaintiff
7 were expected to and did reach Plaintiff without a substantial change in its condition as designed,
8 manufactured, handled, distributed, and sold by Defendants.
9

10 142. At all relevant times, Defendants knew or had reason to know that their Contaminated
11 Baby Food products were defective and were inherently dangerous and unsafe when used in the
12 manner instructed and provided by Defendants.

13 143. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
14 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold
15 and marketed by Defendants were defective in design and formulation, in one or more of the
16 following ways:
17

18 A. When placed in the stream of commerce, Defendants' Contaminated Baby Food products
19 were unreasonably dangerous in that they contained Toxic Heavy Metals that posed a risk
20 of causing interference with neurodevelopment in babies that manifests as the
21 neurodevelopmental disorders ASD, ADHD and related sequelae when used in a
22 reasonably anticipated manner;
23

24 B. When placed in the stream of commerce, Defendants' designed Contaminated Baby Food
25 products to contain unreasonably dangerous design defects and were not reasonably safe
26 when used in a reasonably anticipated or intended manner;
27
28

1 C. Defendants, by design, did not sufficiently test, investigate, or study their Contaminated
2 Baby Food products;

3 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby Food products
4 present a risk of harmful effects that outweigh any potential utility stemming from their
5 use;

6 E. Defendants, by design, did not conduct adequate post-marketing surveillance of their
7 Contaminated Baby Food products which would have alerted the public to risks; and

8 F. Defendants could have employed safer alternative designs and formulations for
9 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable
10 level of Toxic Heavy Metals.
11

12
13 144. Plaintiff consumed Defendants' Contaminated Baby Food products in an intended or
14 reasonably foreseeable manner without knowledge of their dangerous characteristics.

15
16 145. Defendants' Contaminated Baby Food products were and are more dangerous than
17 alternative products, and Defendants could have designed their Contaminated Baby Food products to
18 avoid harm to children. Indeed, at the time Defendants designed the Contaminated Baby Food
19 products, the state of the industry's scientific knowledge was such that a less risky design or
20 formulation was attainable.
21

22 146. At the time the Contaminated Baby Food products left Defendants' control, there was
23 a practical, technically feasible, and safer alternative design that would have prevented the harm
24 without substantially impairing the reasonably anticipated or intended function of Defendants'
25 Contaminated Baby Foods.

26 147. Defendants intentionally and recklessly defectively designed the Contaminated Baby
27 Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice,
28

1 placing their economic interests above the health and safety of Plaintiff.

2 148. The design defects in Defendants' Contaminated Baby Foods were substantial factors
3 in causing Plaintiff's injuries.

4 149. As a direct and proximate result of the Defendants' defective design of the
5 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
6 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
7 but not limited to medical expenses, lost income, and other damages.

8 150. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
9 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
10 such other and further relief as this Court deems just and proper.

11 **IV. COUNT IV: NEGLIGENCE – FAILURE TO WARN**

12 151. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
13 if fully stated herein.

14 152. At all relevant times, Defendants engaged in the business of testing, developing,
15 designing, manufacturing, marketing, selling, distributing, and promoting baby foods. Defendants
16 knew, or, by the exercise of reasonable care, should have known that their Contaminated Baby
17 Foods are not accompanied with adequate warnings concerning the dangerous characteristics of
18 exposure to Toxic Heavy Metals from consumption. These actions were under the ultimate control
19 and supervision of Defendants.

20 153. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
21 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their
22 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products
23 to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks

1 associated with the presence of and exposure to Toxic Heavy Metals from consumption of
2 Contaminated Baby Foods.

3 154. At all relevant times, Defendants had a duty to properly test, develop, design,
4 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
5 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did not
6 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a
7 continuing duty to warn Plaintiff of dangers associated with the presence of and exposure to Toxic
8 Heavy Metals from consumption of Contaminated Baby Foods. Defendants, as a manufacturer,
9 seller, or distributor of food products, are held to the knowledge of an expert in the field.
10

11 155. At the time of manufacture, Defendants could have provided warnings regarding the
12 presence of and risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
13 Foods because they knew or should have known exposure to Toxic Heavy Metals from consumption
14 of Contaminated Baby Foods was dangerous, harmful and injurious when the Contaminated Baby
15 Foods were consumed by Plaintiff in a reasonably foreseeable manner.
16

17 156. At all relevant times, Defendants failed and deliberately refused to investigate, study,
18 test, or promote the safety or to minimize the dangers to users and consumers of their products and
19 to those who would foreseeably use or be harmed by Defendants' Contaminated Baby Foods.
20

21 157. Defendants knew or should have known that exposure to Toxic Heavy Metals from
22 consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise reasonable
23 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.
24 The dangerous propensities of exposure to Toxic Heavy Metals from consumption of the
25 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically
26 knowable to Defendants through appropriate research and testing by known methods, at the time
27
28

1 they distributed, supplied, or sold the products, and were not known to end users and consumers,
2 such as the Plaintiff.

3 158. At all relevant times, Plaintiff was exposed to Toxic Heavy Metals through
4 consumption of the Contaminated Baby Foods while using the products for their intended or
5 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.
6

7 159. Defendants knew or should have known that the non-extant warnings disseminated
8 with their Contaminated Baby Foods were inadequate, failed to communicate adequate information
9 on the presence of and dangers of exposure to toxins contained therein, and failed to communicate
10 warnings and instructions that were appropriate and adequate to render the products safe for their
11 ordinary, intended and reasonably foreseeable uses.
12

13 160. The information that Defendants did provide or communicate failed to contain
14 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
15 avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals contained
16 therein. Instead, Defendants disseminated information that was inaccurate, false, and misleading,
17 and which failed to communicate accurately or adequately the comparative severity, duration, and
18 extent of the risk of injuries with use of and/or exposure to the Toxic Heavy Metals in the
19 Contaminated Baby Foods; continued to aggressively promote the efficacy of their products, even
20 after they knew or should have known of the unreasonable risks from use or exposure to the toxins
21 contained therein; and concealed, downplayed, or otherwise suppressed, through aggressive
22 marketing and promotion, any information or research about the risks and dangers of exposure to
23 Toxic Heavy Metals from consumption of the Contaminated Baby Foods.
24

25 161. A reasonable company under the same or similar circumstance would have warned
26 and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of Contaminated
27
28

1 Baby Foods.

2 162. This alleged failure to warn is not limited to the information contained on the labeling
3 of Defendants' Contaminated Baby Foods. Defendants were able, in accord with federal law, to
4 comply with relevant state law by disclosing the known risks associated with exposure to Toxic
5 Heavy Metals from consumption of Contaminated Baby Foods through other non-labeling mediums,
6 i.e., promotion, advertisements, public service announcements, and/or public information sources.
7 But the Defendants did not disclose these known risks through any medium.
8

9 163. Furthermore, Defendants possess a First Amendment Right to make truthful
10 statements about the products they sell, and no law could lawfully restrict that constitutional right.
11

12 164. Had Defendants provided adequate warnings and instructions and properly disclosed
13 and disseminated the risks associated with the presence of and exposure to Toxic Heavy Metals in
14 the Contaminated Baby Foods, Plaintiff could have avoided the risk of developing injuries and could
15 have obtained or used alternative products. However, as a result of Defendants' concealment of the
16 dangers posed by their Contaminated Baby Foods, Plaintiff could not have averted their injuries.
17

18 165. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
19 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
20 associated with Contaminated Baby Foods, and suppressed this knowledge from the general public.
21 Defendants made conscious decisions not to warn or inform the unsuspecting public.
22

23 166. The Defendants' lack of adequate warnings and instructions accompanying their
24 Contaminated Baby Foods were a substantial factor in causing Plaintiff's injuries.

25 167. As a direct and proximate result of the Defendants' failure to provide an adequate
26 warning of the risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
27 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
28

1 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
2 and future medical expenses, lost income, and other damages.

3 168. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
4 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
5 such other and further relief as this Court deems just and proper.
6

7 **V. COUNT V: NEGLIGENCE - MANUFACTURING**

8 169. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
9 if fully stated herein.
10

11 170. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
12 distributed the Contaminated Baby Foods that Plaintiff consumed.

13 171. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
14 marketing, sale, and distribution of baby foods.

15 172. The Defendants knew or, by the exercise of reasonable care, should have known, that
16 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods rendered the foods
17 carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably
18 foreseeable manner.
19

20 173. The Defendants knew or, by the exercise of reasonable care, should have known,
21 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of
22 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.
23

24 174. Without limitation, examples of the manner in which Defendants breached their duty
25 to exercise reasonable care in manufacturing Contaminated Baby Foods, included:

- 26 A. Failure to adequately inspect/test the Contaminated Baby Foods, and their ingredients,
27 during and after the manufacturing process;
28

1 B. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in
2 baby foods;

3 C. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of
4 ingredients containing Toxic Heavy Metals; and

5
6 D. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy
7 Metals to manufacture baby food.

8 175. A reasonable manufacturer under the same or similar circumstances would have
9 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
10 product.

11
12 176. Plaintiff was harmed directly and proximately by the Defendants' failure to use
13 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes
14 exposure to Toxic Heavy Metals, which can cause or contribute to interference with early
15 neurodevelopment which manifests as ASD, ADHD, and related *sequelae*.

16
17 177. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,
18 and conducted with reckless disregard for the health and safety of users of the Contaminated Baby
19 Foods, including Plaintiff.

20 178. The defects in Defendants' Contaminated Baby Foods were substantial factors in
21 causing Plaintiff's injuries.

22
23 179. As a direct and proximate result of the Defendants' improper manufacturing of
24 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
25 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
26 but not limited to past and future medical expenses, lost income, and other damages.

27
28 180. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in

1 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
2 such other and further relief as this Court deems just and proper.

3 **VI. COUNT VI: NEGLIGENCE – PRODUCT DESIGN**

4
5 181. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
6 if fully stated herein.

7 182. Defendants knew or, by the exercise of reasonable care, should have known, ordinary
8 consumers such as Plaintiff would not have realized the potential risks and dangers of Contaminated
9 Baby Foods.

10
11 183. The Defendants owed a duty to all reasonably foreseeable users to design a safe
12 product.

13 184. The Defendants breached their duty by failing to use reasonable care in the design of
14 Contaminated Baby Foods because the products exposed babies to Toxic Heavy Metals.

15
16 185. The Defendants breached their duty by failing to use reasonable care in the design of
17 Contaminated Baby Foods by negligently designing the foods with ingredients and/or components
18 contaminated with Toxic Heavy Metals.

19 186. The Defendants breached their duty by failing to use reasonable care in the design of
20 Contaminated Baby Foods by negligently designing and formulation, in one or more of the
21 following ways:

22
23 A. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
24 defective in design and formulation, and, consequently, dangerous to an extent beyond
25 that which an ordinary consumer would contemplate;

26 B. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
27 unreasonably dangerous in that they were hazardous and posed a risk of
28

1 neurodevelopmental disorders and other serious illnesses when used in a reasonably
2 anticipated manner;

3 C. When placed in the stream of commerce, Defendants' Contaminated Baby Foods
4 contained unreasonably dangerous design defects and were not reasonably safe when
5 used in a reasonably anticipated or intended manner;

6
7 D. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
8 and, specifically, the content of Toxic Heavy Metals in the ingredients used to
9 manufacture the foods and/or the finished products;

10
11 E. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
12 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals; and

13 F. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of
14 harmful effects that outweigh any potential utility stemming from the use of the products;

15
16 187. Defendants knew or should have known at the time of marketing Contaminated Baby
17 Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in interference
18 with early neurodevelopment that that manifests as ASD, ADHD and other severe illnesses and
19 injuries.

20 188. Defendants, by design, did not conduct adequate post-marketing surveillance of their
21 Contaminated Baby Foods.

22
23 189. Defendants could have employed safer alternative designs and formulations. For
24 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic
25 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or
26 sampled their ingredients from other sources.

27
28 190. The Defendants breached their duty by failing to use reasonable care by failing to use

1 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible,
2 and safer alternative design that would have prevented the harm without substantially impairing the
3 reasonably anticipated or intended function of Defendants' Contaminated Baby Foods.

4 191. A reasonable company under the same or similar circumstances would have designed
5 a safer product.
6

7 192. Plaintiff was harmed directly and proximately by the Defendants' failure to use
8 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure to
9 Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment that
10 manifests as ASD, ADHD, and related *sequelae*.
11

12 193. Defendants' defective design of Contaminated Baby Foods was willful, wanton,
13 malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby
14 Foods, including Plaintiff.
15

16 194. The defects in Defendants' Contaminated Baby Foods were substantial factors in
17 causing Plaintiff's injuries.

18 195. As a direct and proximate result of the Defendants' negligent design of the
19 Contaminated Baby Foods, Plaintiff have been injured, sustained severe and permanent pain,
20 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including,
21 but not limited to past and future medical expenses, lost income, and other damages.
22

23 196. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
24 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
25 such other and further relief as this Court deems just and proper.

26 **VII. COUNT VII: GENERAL NEGLIGENCE**
27

28 197. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as

1 if fully stated herein.

2 198. Plaintiff pleads claims for negligence under all theories that may be actionable under
3 New York state laws.

4 199. Defendants owed Plaintiff a duty to act with reasonable care.

5
6 A. Defendants owed a duty because they distributed and promoted their products as safe for
7 children to consume.

8 B. Defendants owed a duty because their conduct created a risk of harm to Plaintiff and caused
9 Plaintiff actual harm.

10 C. Defendants owed a duty because the risk of harm to Plaintiff was embedded in, and an
11 inherent component of, their negligent business practices.

12 D. Defendants owed a duty because they designed, manufactured, controlled, distributed, and
13 sold their products to Plaintiff.

14
15 200. Defendants breached their duty to Plaintiff.

16
17 201. Defendants' negligence includes, but is not limited to, their marketing, designing
18 manufacturing, producing, supplying, inspecting, testing, selling and/or distributing Contaminated
19 Baby Foods in one or more of the following respects:

20 A. Failure to implement procedures that would reduce or eliminate Toxic Heavy Metals in baby
21 foods;

22 B. Failure to investigate suppliers and ingredient sources to reduce and eliminate the risk of
23 ingredients containing Toxic Heavy Metals; and

24 C. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to
25 manufacture baby food.
26
27
28

1 D. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
2 defective in design and formulation, and, consequently, dangerous to an extent beyond that
3 which an ordinary consumer would contemplate;

4
5 E. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were
6 unreasonably dangerous in that they were hazardous and posed a risk of neurodevelopmental
7 disorders and other serious illnesses when used in a reasonably anticipated manner;

8 F. When placed in the stream of commerce, Defendants' Contaminated Baby Foods contained
9 unreasonably dangerous design defects and were not reasonably safe when used in a
10 reasonably anticipated or intended manner;

11
12 G. Defendants, by design, did not conduct adequate post-marketing surveillance of their
13 Contaminated Baby Food products which would have alerted the public to risks; and

14 H. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
15 and, specifically, the ability for those foods to expose babies to Toxic Heavy Metals;

16
17 I. Defendants could have employed safer alternative designs and formulations for
18 Contaminated Baby Foods, such as ensuring the baby food did not have any detectable level
19 of Toxic Heavy Metal.

20 J. Defendants did not sufficiently test, investigate, or study their Contaminated Baby Foods
21 and, specifically, the content of Toxic Heavy Metals in the ingredients used to manufacture
22 the foods and/or the finished products; and

23
24 K. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods presents a risk of harmful
25 effects that outweigh any potential utility stemming from the use of the products;

26
27 202. Defendants knew or should have known that their products contained detectable
28 levels of heavy metals that created an unreasonable risk of harm to children who consumed their

1 products.

2 203. At all relevant times, the Defendants knew or should have known that the Products
3 were unreasonably dangerous and defective when put to their reasonably anticipated use.

4 204. As a proximate result of Defendants' negligence, Plaintiff has been injured, sustained
5 severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic
6 loss, and damages including, but not limited to past and future medical expenses, lost income, and
7 other damages.
8

9 205. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
10 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all
11 such other and further relief as this Court deems just and proper.
12

13
14 **JURY TRIAL DEMAND**

15 206. Plaintiff demands a trial by jury on all the triable issues within this pleading.
16

17 **PRAYER FOR RELIEF**

18 207. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's favor
19 and against the Defendants for:

- 20 **a.** actual or compensatory damages in such amount to be determined at trial and as provided
21 by applicable law;
22 **b.** exemplary and punitive damages sufficient to punish and deter the Defendants and others
23 from future wrongful practices;
24 **c.** pre-judgment and post-judgment interest;
25 **d.** costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
26 **e.** any other relief the Court may deem just and proper.
27
28

1 DATED this 8th Day of November, 2024.

CHAFFIN LUHANA LLP

2
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